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On

April 19, 2007

Date of Deposit

Richard E. Stanley, Jr., Reg. No. 45,662

Name of Applicant, Assignee or  
Registered Representative

Signature

April 19, 2007

Date of Deposit

Our Case No. 8627-51  
Client Ref. No. PA-5322-RFB

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Brian Bates

Serial No. 10/092,095

Filing Date: March 6, 2002

For PARTIALLY COVERED  
INTRALUMINAL SUPPORT  
DEVICE

Examiner: Sarah K. Webb

Group Art Unit No.: 3731

### PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action dated February 2, 2007, Applicant requests review of the rejections in the above-identified application. Applicant's claims have been rejected at least twice by the Examiner. Therefore, Applicant is entitled to appeal the present application regardless of whether the claims are presently subject to a final rejection. MPEP § 1204. A Notice of Appeal accompanies this Request. The fee for

the Notice of Appeal was paid by Applicant on November 3, 2006, in connection with the first pre-appeal brief. Therefore, no fee is believed to be due in connection with Applicant's current pre-appeal brief. However, should any fees be deemed necessary for any reason relating to these materials, the Commissioner is hereby authorized to deduct said fees from Brinks Hofer Gilson & Lione Deposit Account No. 23-1925. As explained in more detail below, this review is being requested because of clear errors in the Examiner's rejections, and the Examiner's omission of essential elements needed for a prima facie rejection.

### **Status of the Claims**

Claims 40-50 and 73-74 are pending in the application. The most recent listing of the claims is included with Applicant's RCE filed on December 13, 2005. Claim 40 is the only independent claim. Prior to the present Office Action, the Examiner rejected the claims under 35 U.S.C. § 103(a) based on Summers, McCrory, Myers et al. and Wulfman et al. In response to that rejection, Applicant filed a Pre-Appeal Brief on November 3, 2006. As a result of Applicant's Pre-Appeal Brief, the Examiner withdrew the prior claim rejections and issued a new rejection under 35 U.S.C. § 103(a) based on Summers, Davila et al., McCrory, and Wulfman et al.

Essentially, the Examiner's previous rejection and the present rejection are identical, except that Davila et al. has been substituted for Myers et al. In the present Office Action, the Examiner admits that Applicant's arguments against the Myers et al. reference were persuasive. If that is the case, then Applicant's claims should be allowable because Davila et al. is no more relevant to Applicant's claims than Myers et al.

### **Argument**

Applicant contends that the Examiner has used impermissible hindsight to piece the prior art together like a jigsaw puzzle to achieve Applicant's invention. The Examiner has not articulated a proper motivation to combine the cited prior art in the proposed manner. As such, the Examiner has not established a prima facie case of obviousness.

35 U.S.C. § 103 requires that the subject matter of the claimed invention be considered “as a whole.” The ultimate question under 35 U.S.C. § 103 is “whether the claimed invention as a whole would have been obvious,” “not whether the differences [between the claimed invention and the prior art] themselves would have been obvious.” *Stratoflex*, 713 F.2d at 1537 (Fed. Cir. 1983); *Schenk*, 713 F.2d at 785 (Fed. Cir. 1983). “To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.” *In re Rouffet*, 149 F.3d at 1357 (Fed. Cir. 1998).

“That all elements of an invention may have been old (the normal situation), or some old and some new, or all new, is however, simply irrelevant. Virtually all inventions are combinations of old elements. A court must consider what the prior art as a whole would have suggested to one skilled in the art.” *Environmental*, 713 F.2d at 698 (Fed. Cir. 1983). “The ‘as a whole’ instruction in title 35 prevents evaluation of the invention part by part. Without this important requirement, an obviousness assessment might break an invention into its component parts (A + B + C), then find a prior art reference containing A, another containing B, and another containing C, and on that basis alone declare the invention obvious. This form of hindsight reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new result—often the very definition of invention.” *Ruiz*, 357 F.3d at 1275 (Fed. Cir. 2004).

“This line of reasoning would import hindsight into the obviousness determination by using the invention as a roadmap to find its prior art components. Further, this improper method would discount the value of combining various existing features or principles in a new way to achieve a new result—often the essence of invention.” *Princeton*, 411 F.3d at 1337 (Fed. Cir. 2005).

Contrary to the admonitions of the Federal Circuit, Applicant contends that the Examiner has engaged in impermissible hindsight to reconstruct Applicant’s invention

piece-by-piece from the prior art using Applicant's claims as a roadmap. Like the example given in *Ruiz v. A.B. Chance*, the Examiner has broken Applicant's claims into component parts A, B and C to declare the claims obvious. In the Examiner's analysis, component A is the structure of the stent (Summers). Component B according to the Examiner is the graft layer (McCrory). Component C according to the Examiner is the manner of attaching the graft layer to the stent (Davila et al.). Using hindsight and the Applicant's claims as a roadmap, the Examiner has combined components A, B and C of Summers, McCrory and Davila et al. to reconstruct Applicant's claims.

As noted above, the Examiner has already admitted that Applicant's arguments are persuasive in overcoming Summers, McCrory and Myers et al. (Office Action at 4). In place of that rejection, the Examiner has substituted Davila et al. for Myers et al. However, Davila et al. is no more relevant to the claimed invention than Myers et al. Thus, the Examiner's new rejection based on Summers, McCrory and Davila et al. should be withdrawn and the claims should be allowed.

Importantly, Myers et al. and Davila et al. do not disclose that the attachment mechanism can be used for a partially coated stent. Indeed, both references disclose stents that are completely covered by the graft material. There is absolutely no disclosure of a partially coated stent in Myers et al. or Davila et al.


Moreover, the stent structures of Myers et al., Davila et al. and McCrory are completely different from the claimed invention. As previously argued, McCrory does not disclose the stent structure claimed by Applicants because McCrory discloses a mesh stent. By contrast, Applicant's claims specifically recite a "non-mesh tubular structure formed of one or more frame threads circumferentially wrapped thereabout."

The stent structures disclosed in Myers et al. and Davila et al. are both z-stents, which are neither mesh structures like McCrory or the claimed stent structure that has circumferentially wrapped frame threads. Indeed, the stent structure disclosed in Davila et al. is less relevant to the claimed stent structure than Myers et al. In Davila et al., the stent graft actually comprises two different stents. As shown in Figure 7, stent 80 is disposed within stent 60. (See also Figures 6 and 9E; col. 5, lines 21-23; col. 10, lines 18, 24-25). The graft layer is disposed between stent 80 and stent 60.

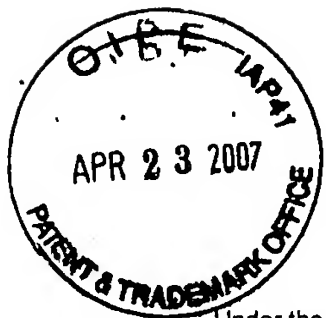
There is no suggestion or motivation that Davila et al. could be used for a partially coated stent graft as claimed by Applicant. Moreover, there is no suggestion or motivation that Davila et al. could be used with the claimed stent structure, which is entirely different from the stent structure that is claimed. The references that the Examiner relies upon simply do not relate to the claimed invention. Applicant respectfully submits that the Examiner's arguments are based upon an improper hindsight reconstruction of Applicant's invention.

Because the Examiner's rejection does not set forth a proper prima facie case of obviousness, Applicant requests that the rejections in the application be withdrawn and a notice of allowance granted.

Respectfully submitted,

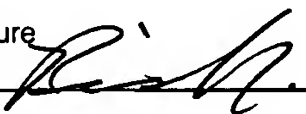
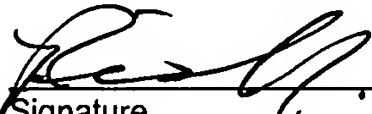
  
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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 8627-051 (PA-5322-RFB)	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" (37 CFR 1.8(a)). On <u>April 19, 2007</u> Signature <u></u> Typed or printed Name <u>Richard E. Stanley, Jr.</u>	Application Number <b>10/092,095</b>	Filed <b>March 6, 2002</b>	
	First Named Inventor <b>Brian Bates</b>		
	Art Unit <b>3731</b>	Examiner <b>WEBB, Sarah K.</b>	
<p>Applicant requests review of the rejection in the above-identified application. Applicant's claims have been rejected at least twice by the Examiner. Therefore, Applicant is entitled to file an appeal of the rejection. No amendments are being filed with this request.</p> <p>This request is being filed with a Notice of Appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five(5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>45,662</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. <u>          </u></p> <p>Note: Signatures of all inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.*</p> <p><input type="checkbox"/> *Total of <u>      </u> forms are submitted.</p>			
		<u></u> Signature	
		<u>Richard E. Stanley, Jr.</u> Typed or Printed Name	
		<u>(312) 321-4200</u> Telephone number	
		<u>April 19, 2007</u> Date	